requirements of CFPB's Regulation B is mandatory. Because the recordkeeping and disclosure requirements of the CFPB's Regulation B require creditors to retain their own records and to make certain disclosures to customers, the Freedom of Information Act (FOIA) would only be implicated if the Board's examiners retained a copy of this information as part of an examination of a bank. Records obtained as a part of an examination or supervision of a bank are exempt from disclosure under FOIA exemption (b)(8), for examination material (5 U.S.C. 552(b)(8)). In addition, the records may also be exempt under FOIA exemption (b)(4) or (b)(6). Records would be exempt under (b)(4) if the records contained ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential'' and the disclosure of the information is likely to cause substantial harm to the competitive position of the respondents (5 U.S.C. 552(b)(4)). Records would be exempt under (b)(6) if the records contained personal information, the disclosure of which would ''constitute a clearly unwarranted invasion of personal privacy'' (5 U.S.C. 552(b)(6)).

Current actions: On April 13, 2018, the Board published a notice in the **Federal Register** (83 FR 16098) requesting public comment for 60 days on the extension, without revision, of the FR B. The comment period for this notice expired on June 12, 2018. The Board received one comment letter that addressed matter outside the scope of this proposal.

Board of Governors of the Federal Reserve System, June 28, 2018.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2018–14305 Filed 7–2–18; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2018–0006; Docket Number NIOSH–306]

Final National Occupational Research Agenda for Services

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: NIOSH announces the availability of the final *National Occupational Research Agenda for Services.*

DATES: The final document was published on June 26, 2018.

ADDRESSES: The document may be obtained at the following link: *https://www.cdc.gov/niosh/nora/sectors/serv/agenda.html.*

FOR FURTHER INFORMATION CONTACT: Emily Novicki, M.A., M.P.H, (*NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: On January 29, 2018, NIOSH published a request for public review in the **Federal Register** [83 FR 4058] of the draft version of the *National Occupational Research Agenda for Services.* All comments received were reviewed and addressed where appropriate.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–14227 Filed 7–2–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10673]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by September 4, 2018.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ___, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10673 Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management

and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New Collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration; *Use:* The Centers for Medicare & Medicaid Services (CMS) may test a demonstration, under Section 402 of the Social Security Amendments of 1968 (as amended), entitled the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration (''the Demonstration''). If it goes forward, the MAQI demonstration could test whether exempting, through the use of waiver authority, clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) (combined with participation, if any, in Advanced Alternative Payment Models (APMs) with Medicare Fee-for-Service (FFS)) from the Merit-based Incentive Payment System (MIPS) reporting requirements and payment adjustment will increase or maintain participation in payment arrangements with MAOs similar to Advanced APMs and change the manner in which clinicians deliver care.

Clinicians may currently participate in one of two paths of the Quality Payment Program (QPP): (1) MIPS, which adjusts Medicare payments based on combined performance on measures of quality, cost, improvement activities, and advancing care information, or (2) Advanced Alternative Payment Models with Medicare (Advanced APMs), under which eligible clinicians may earn an incentive payment for sufficient participation in certain payment arrangements with Medicare fee-for-service (FFS) and other payers, and starting in the 2019 performance period, with other payers such as Medicare Advantage, commercial payers, and Medicaid managed care. To participate in the Advanced APM path of QPP for a given year, eligible clinicians must meet the criteria of Qualifying APM Participants (QPs); in addition to earning an APM incentive payment, QPs are excluded from the MIPS reporting requirements and payment adjustment.

An eligible clinician that does not meet the criteria to be a QP for a given year will be subject to MIPS for that year unless the clinician meets certain other MIPS exclusion criteria, such as being newly enrolled in Medicare or meeting the low volume threshold for Medicare FFS patients. The MAQI Demonstration could allow participating clinicians to have the opportunity to be exempt from MIPS reporting and payment consequences for a given year if they participate to a sufficient degree in certain Qualifying Payment Arrangements with MAOs (and Advanced APMs with Medicare FFS) during the performance period for that year, without requiring them to be QPs or otherwise meet the MIPS exclusion criteria of QPP. Under a possible Demonstration, clinicians might not be required to have a minimum amount of participation in an Advanced APM with Medicare FFS in order to be exempt from MIPS reporting requirements and payment adjustments for a year, but if they did have participation in Advanced APMs with Medicare FFS, that participation could also be counted towards the thresholds that trigger the waiver from MIPS reporting and payment consequences. In addition, the Demonstration could permit consideration of participation in ''Qualifying Payment Arrangements'' with Medicare Advantage plans that meet the criteria to be Other Payer Advanced APMs a year before the All-Payer Combination Option is available.

In the Calendar Year 2018 Quality Payment Program Final Rule, CMS noted its intention ''to develop a demonstration project to test the effects of expanding incentives for eligible clinicians to participate in innovative alternative payment arrangements under Medicare Advantage that qualify as Advanced APMs, by allowing credit for participation in such Medicare Advantage arrangements prior to 2019 and incentivizing participation in such arrangements in 2018 through 2024.'' (92 FR 53865).

The first performance period for the Demonstration is tentatively planned for 2018 and the Demonstration would last up to five years. Clinicians who meet the definition of MIPS eligible clinician under QPP as defined under 42 CFR 414.1305 would be eligible to participate in the MAQI Demonstration. Currently, MIPS eligible clinicians include physicians (including doctors of medicine, doctors of osteopathy, osteopathic practitioners, doctors of dental surgery, doctors of dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists. If the definition of MIPS eligible clinician changes under future rulemaking, the Demonstration would use the updated definition to define Demonstration eligibility.

Participation could last the duration of the Demonstration, unless participation is voluntarily or involuntarily terminated under the terms and conditions of the Demonstration. Participants would have the opportunity to submit the required documentation and be evaluated for MIPS waivers through the Demonstration each year.

Should this demonstration move forward, and in order to conduct an evaluation and effectively implement the MAQI Demonstration, CMS would need to collect information from Demonstration participants on (a) payment arrangements with MAOs and (b) Medicare Advantage (MA) payments and patient counts. CMS would require a new collection of this information as this information is not already available through other sources and/or has not been previously approved for use under the MAQI Demonstration. The information collected in these forms would allow CMS to evaluate whether the payment arrangement that clinicians have with MAOs meet the Qualifying Payment Arrangement criteria, and determine whether a clinician's MAO and FFS APM patient population or payments meet demonstration thresholds. Both of these areas are also requirements for review and data collection under QPP (*i.e.* the Eligible Clinician-Initiated Other Payer Advanced APM Determination form and All-Payer QP Submission form), and therefore similar to forms have been prepared and reviewed under the QPP.

Given these similarities in forms, burden estimates for the MAQI Demonstration PRA package were derived from burden analyses and formulation done in conjunction with the QPP forms; more specifically the estimated burden associated with the submission of payment arrangement information for Other Payer Advanced APM Determinations: Eligible Clinician-Initiated Process, and the estimated burden associated with the submission of data for All-Payer QP determinations. CMS estimates the total hour burden per

respondent for the MAQI demonstration to be 15 hours, to match the hours listed in the equivalent QPP forms. Full detail of how these estimates were derived can be found in the forthcoming Calendar Year 2019 Proposed QPP rule.

If Demonstration participants submitted information, but did not meet these conditions of the Demonstration, their participation in the Demonstration would not be terminated, but they would not receive the waivers from MIPS reporting requirements and payment adjustments. Therefore, unless they become QPs or are excluded from MIPS for other reasons, the participating clinicians would be subject to MIPS and would face the MIPS payment adjustments for the applicable year. We are requesting approval of 2 information collections associated with the MAQI Demonstration: (a) A Qualifying Payment Arrangement Submission Form and (b) a Threshold Data Submission Form. *Form Number:* CMS–10673 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 100,000; *Total Annual Responses*: 100,000; *Total Annual Hours:* 1,500,000. (For policy questions regarding this collection contact John Amoh at *john.amoh@cms.hhs.gov*.)

Dated: June 28, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–14336 Filed 6–29–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2012–N–0129]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in an application for a proposed biosimilar product and an application for a supplement for a proposed interchangeable product.

DATES: Submit either electronic or written comments on the collection of information by September 4, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 4, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 4, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA 2012–N–0129 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management